



# **Material Safety Data Sheet**

***Anti-HBc IgG ELISA***

***Catalog Number: 68-4CBE3***

## **ALPCO Diagnostics**

**26G Keewaydin Drive • Salem, NH 03079**  
**Phone: (800) 592-5726 • Fax: (603) 898-6854**  
**[www.alpco.com](http://www.alpco.com) • Email: [web@alpco.com](mailto:web@alpco.com)**

**1) Product and company identification:****Product:** In Vitro Reagents **Product Code:** 4CBE3**Company:** GENERAL BIOLOGICALS CORP.**Address of the company:** #6, INNOVATION FIRST ROAD, SCIENCE PARK, HSIN CHU, TAIWAN, R.O.C.**Telephone Number for emergency of the company:** 886-3-5779221-254**Fax number of the company:** 886-3-5779227 **E mail of the company:** SALE.GROUP@gbc.com.tw**2) Composition/information on ingredients:****2.1) Chemical Characterization:** preparation**2.2) Description:** Kit of components listed below with non-hazardous additions.

No.	Components	Physical appearance	96-tests
1	HBcAg Plate	Solidin aluminum foil	1 plate
2	Anti-HBc HRPO Solution	Liquid in plastic bottle	1 bottle, 7 ml/btl
3	HB Negative Control	Liquid in plastic bottle	1 bottle, 1.5 ml/btl
4	Anti-HBc IgG Positive Control	Liquid in plastic bottle	1 bottle, 1 ml/btl
5	Washing Solution D (20X)	Liquid in plastic bottle	1 bottle, 52 ml/btl
6	TMB substrate Solution A	Liquid in plastic bottle	1 bottle, 10 ml/btl
7	TMB Substrate Solution B	Liquid in plastic bottle	1 bottle, 10 ml/btl
8	2N Sulfuric Acid	Liquid in plastic bottle	1 bottle, 12 ml/btl

**2.3) Dangerous Components:**

Component	CAS No.	Ingredient	Content	S phrases	R phrases
(2)	Not found	Human/Animal Sourced Preparation	40%	Not found	Not found
	77-86-1	Tris	<2 %	26-36	36/37/38
	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	54-64-8	Thimerosal	<0.1 %	13-28-36-45	26/27/28-33
	Not found	Horse-radish peroxidase	Trace	Not found	Not found
(3)	Not found	Human/Animal Sourced Preparation	100%	Not found	Not found
	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	54-64-8	Thimerosal	<0.1 %	13-28-36-45	26/27/28-33
(4)	Not found	Human/Animal Sourced Preparation	100%	Not found	Not found
	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	54-64-8	Thimerosal	<0.1 %	13-28-36-45	26/27/28-33


Component	CAS No.	Ingredient	Content	S phrases	R phrases
(5)	54827-17-7	3,3',5,5'-Tetramethylbenzidine	<0.04 %	26-22-36	20/21/22-36/37/ 38-40
	67-68-5	Dimethyl sulfoxide	<5 v/v%	26-36-23	36/37/38
	67-56-1	Methanol	5 v/v %	7-16-24-45	11-23/25
	56-81-5	Glycerol	<15 v/v %	26-36	36/38
(6)	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	7722-84-1	Hydrogen peroxide	< 0.1%	17-45-26-36/37 /39	8-34
(8)	7664-93-9	Sulfuric Acid	<6 v/v %	26-30-45	35

**2.4) Additional Information:**







The components 1. to 4 contain materials of human or animal origin. Since no test method offers complete assurance that infectious agents are absent, these components should be handled as potential infectious.

3) Hazards Identification:





3.1) Hazard description:

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Human/ Animal Sourced Preparation Potential Biohazard		1. Inhalation 2. Skin contact 3. Eye contact 4. Ingestion	Potential biohazard	Potential biohazard, should be autoclaved before disposal.	No
					
Tris Buffer		1. Skin contact  2. Eye contact  3. Ingestion	1. May cause irritation to skin. Symptoms include redness, itching, and pain.  2. May cause irritation, redness, and pain.  3. May be harmful, cause irritation and reddening to the mucous membranes. Symptoms may include nausea, vomiting and diarrhea.  Estimated lethal dose: 50 gm.	No (concentration <2 %)	No (Aqueous solution)
					





To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Gentamycin Sulfate in Solution Irritation	 Harmful or Irritant	1. Skin contact  2. Eye contact  3. Ingestion	1. May cause skin irritation: redness or itching. May cause systemic poisoning.  2. May cause eye irritation/sensitization. May cause systemic poisoning.  3. May be harmful, cause irritation to the mucous membranes. May cause systemic poisoning.	No (concentration <0.01 %)	No (Aqueous solution)
					
Thimerosal in Solution Harmful	 Harmful or Irritant	1. Skin contact  2. Eye contact  3. Ingestion	1. May be harmful through skin contact.  2. May be harmful through eyes contact.  3. Harmful by ingestion, ORL Rat LD <sub>50</sub> : 75mg/kg <sup>-1</sup> .	Contains mercury (C <sub>9</sub> H <sub>9</sub> HgNaO <sub>2</sub> S concentration <0.1 %)	No (Aqueous solution)
					
Horse-radish peroxidase Solution Irritation		1. Skin contact	a. There is at present no information or indication of hazardous property.	No (concentration is very low)	No (Aqueous solution)
		2. Eye contact	b. May cause irritation.		
		3. Ingestion   Harmful or Irritant	c. May cause allergic reaction to a small percentage of the population who exhibit an allergic reaction to enzymes.		


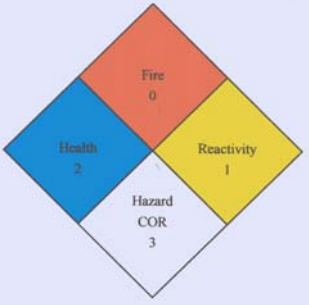
To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
3,3',5,5'-Tetramethyl-Benzidine Solution	Harmful or irritation 	Skin contact Eye contact Ingestion	Harmful, irritation, should be handled as a potential carcinogen.	No (concentration <0.1 %)	No (Aqueous solution containing dimethyl sulfoxide and methyl alcohol)
					
Dimethyl Sulfoxide in Aqueous Solution Irritation		1. Inhalation  2. Skin contact   3. Eye contact  4. Ingestion	1. Irritation, nausea, vomiting, headache, dizziness. 2. Irritation, allergic reactions, blisters, rash, itching, nausea, vomiting, diarrhea, chest pain, headache, drowsiness, blood disorders. 3. Irritation, blurred vision 4. Nausea, vomiting, diarrhea, stomach pain, drowsiness.	No (concentration <5 v/v%)	No (Aqueous solution)
					

To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Methanol Aqueous Solution Irritation Toxic		1. Inhalation  2. Skin contact 3. Eye contact 4. Ingestion	1. Cause irritation to respiratory tract. Affects central nervous system, especially optic nerve. Cause dizziness, nausea, muscle weakness, narcosis, respiratory failure. 2. Cause irritation to skin. 3. Cause irritation to eyes. 4. Harmful if digested. Affects central nervous system, especially optic nerve. Cause dizziness, nausea, muscle weakness, narcosis, respiratory failure. Can produce blindness (100 ml can be fatal).	No (Concentration <45 v/v %)	No (Aqueous solution)
					
Hydrogen peroxide Aqueous Solution (< 0.1%)	Very Mild Oxidizing 	Skin contact Eye contact Ingestion	No	No (concentration < 0.1%)	No (Aqueous solution)
					

To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Dilute Sulfuric Acid Aqueous Solution (<6 v/v %) Corrosive	 <p>Corrosive</p>	1. Inhalation	1. May cause severe irritation of the respiratory tract with sore throat, coughing, shortness of breath and delayed lung edema. May Causes chemical burns to the respiratory tract.	No (concentration <6 v/v %)	No (Aqueous solution)
		2. Skin contact	Inhalation may be fatal as a result of spasm, inflammation, edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema. Aspiration may lead to pulmonary edema. May cause systemic effects.		
		3. Eye contact	2. Causes skin burns. Continued contact can cause tissue necrosis. May cause skin rash, and cold and clammy skin with cyanosis or pale color.		
		4. Ingestion	3. Causes eye burns. May cause chemical conjunctivitis and corneal damage.		
		5. Cancer hazard. Mutation.	4. May cause severe and permanent damage to the digestive tract. Causes gastrointestinal tract burns. May cause systemic toxicity with acidosis. May cause perforation of the digestive tract.		





3.2)

**Classification System:**

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4) **First-aid Measures:**

**General  
Information**

No special  
measures  
required.

Inhalation

**InhalationSu**

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air. Seek  
medical  
advice in  
case of  
complaints.

Supply fresh  
air. Seek  
medical  
advice in  
case of  
complaints.

**Ingestion****IngestionRin**

se mouth  
thoroughly  
with water.

Seek  
medical  
advice in  
case of  
complaints.

Rinse mouth  
thoroughly  
with water.

Seek  
medical  
advice in  
case of  
complaints.

**Contact with  
eyes**

Wash  
with copious  
amounts of  
water. Seek  
medical

advice in

**5) Fire Fighting Measures:****Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray.

Fight larger fires with water spray or alcohol resistant foam.

**Special Protective Equipment:** No special measures required.**Specific Hazards:**

Components	Specific Hazards
1. Plate	CO.
2. HRPO Conjugate Solution	CO, NO <sub>x</sub> , SO <sub>x</sub> , Hg.
3. Negative Control	CO, NO <sub>x</sub> , SO <sub>2</sub> , Hg.
4. Positive Control	CO, NO <sub>x</sub> , SO <sub>x</sub> , Hg.
5. Washing Solution D (20X)	CO.
6. TMB substrate Solution A	CO, NO <sub>x</sub> , SO <sub>x</sub> .
7. TMB Substrate Solution B	CO.
8. 2N Sulfuric Acid	SO <sub>x</sub> .

<p>6) Accidental Release Measures: Personal Precautions:</p>	
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E:

**Environmental Precautions:**

**Methods for Cleaning Up:**

**Components**Methods

**Cleaning Up**

**Methods for Cleaning**

2. HRPO Conjugate S

2. HRPO Conjugate

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Inactivated with Sodi

Hypochlorite Solution

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water.

3. Negative Control

3. Negative Control

4. Positive Control

4. Positive Control

5. Washing Solution

5. Washing Solution

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water.

Clean with plenty of

6. TMB substrate Sol

6. TMB substrate Sol

7. TMB Substrate So

7. TMB Substrate So

8. 2N Sulfuric Acid

8. 2N Sulfuric Acid

<p>7) <b>Handling and Storage:</b></p> <p>7.1) <b>Handling:</b></p> <p><b>Technical Measures:</b> No special measures required.</p> <p><b>Precautions:</b> Handled as biohazards. Wear protective gloves and avoid the generation of aerosols. Keep TMB Solution A away from fire sources.</p> <p><b>Specific Safe Handling Advice:</b> No special measures required.</p> <p>7.2) <b>Storage:</b></p> <p><b>Technical Measures:</b> No special measures required.</p> <p><b>Storage conditions:</b> Store in 2 ~ 8°C.</p> <p><b>Incompatible products:</b> No special measures required.</p> <p><b>Packaging Materials:</b> No special measures required.</p>	
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<p><b>8) Exposure Control/Personal Protection:</b></p> <p><b>8.1) Engineering Measures:</b>  <b>Additional Information</b>  about design of technical facilities: No, see item 7).</p> <p><b>8.2) Specific Control Parameters:</b>  <b>Ingredients with limit values that require monitoring at the workplace:</b> No.  <b>Additional Information:</b>  No special measures required.</p> <p><b>8.3) Personal Protective equipment:</b></p> <p><b>Respiratory Protection:</b>  No special measures required.</p> <p><b>Hand Protection:</b> Wear protective gloves.</p> <p><b>Eye Protection:</b> No special measures required.</p> <p><b>Skin and Body Protection:</b> Wear protective gown.</p> <p><b>8.4) Hygiene Measures:</b>  Handled as biohazards.</p>
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<b>9) Physical and chemical Properties::</b>							
<b>9.1) Physical Properties:</b>							
Component	Form	Color	Odor	m.p.	b.p.	Flash Point	Self-ignition
1. plate	solid	colorless	odorless	N/A	N/A	N/A	N/A
2. HRPO Conjugate Solution	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
3. Negative Control	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
4. Positive Control	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined

5. Washing Solution D (20X)	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
6. TMB substrate Solution A	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
7. TMB Substrate Solution B	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
8. 2N Sulfuric Acid	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined



9.2) Chemical Properties:
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ComponentDanger  
 of explosionDensity  
 Danger of  
 explosionDensity  
 DensitySolubility in  
 waterOrganic  
 Solvents  
 ContentWater  
 content  
 Solubility in  
 waterOrganic  
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**10) Stability and Reactivity:****10.1) Thermal decomposition/Conditions to be avoided:**

Decomposition will not occur if used and stored according to the package insert.

**10.2) Materials to be avoided:**

Please use the kit in accordance with the package insert.

**10.3) Dangerous Reactions:**

No dangerous reactions known.

**10.4) Dangerous decomposition products:**

Components	Dangerous decomposition products
1. Plate	CO.
2. HRPO Conjugate Solution	CO, NO <sub>x</sub> , SO <sub>x</sub> , Hg.
3. Negative Control	CO, NO <sub>x</sub> , SO <sub>2</sub> , Hg.
4. Positive Control	CO, NO <sub>x</sub> , SO <sub>x</sub> , Hg.
5. Washing Solution D (20X)	CO.
6. TMB substrate Solution A	CO, NO <sub>x</sub> , SO <sub>x</sub> .
7. TMB Substrate Solution B	CO.
8. 2N Sulfuric Acid	SO <sub>x</sub> .

<p>11) <b>Toxicological Information:</b> :</p> <p>11.1) <b>Acute Toxicity:</b> Acute toxicity will not occur if used and stored according to the package insert.</p> <p>11.2) <b>Local Effects:</b></p>	
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**ComponentsLocal  
Effects****Local Effects**

1. Plate

1. PlateNo.

No.

2. HRPO Conjugate

SolutionMay cause irritation to skin, mucous membranes and eyes.

2. HRPO Conjugate

SolutionMay cause irritation to skin, mucous membranes and eyes.

May cause irritation to skin, mucous membranes and eyes.

3. Negative Control

3. Negative

ControlMay cause irritation to skin, mucous membranes and eyes.

May cause irritation to skin, mucous membranes and eyes.

4. Positive Control

4. Positive

ControlMay cause irritation to skin, mucous membranes and eyes.

May cause irritation to skin, mucous membranes and eyes.

5. Washing Solution  
D (20X)No.

5. Washing Solution  
D (20X)No



**To be continued**

**11.4) Chronic Toxicity or Long Term Toxicity:**

Components	Chronic Toxicity or Long Term Toxicity
1. Plate	No.
2. HRPO Conjugate Solution	May cause systemic poison.
3. Negative Control	May cause systemic poison.
4. Positive Control	May cause systemic poison.
5. Washing Solution D (20X)	No.
6. TMB substrate Solution A	May affects central nervous system.
7. TMB Substrate Solution B	No.
8. 2N Sulfuric Acid	May cause systemic toxicity with acidosis.

**11.5) Carcinogenicity/Mutagenicity:**

Components	Carcinogenicity/Mutagenicity
1. Plate	Not a carcinogen/mutagen.
2. HRPO Conjugate Solution	Not a carcinogen/mutagen.
3. Negative Control	Not a carcinogen/mutagen.
4. Positive Control	Not a carcinogen/mutagen.
5. Washing Solution D (20X)	Not a carcinogen/mutagen.
6. TMB substrate Solution A	May be a carcinogen/mutagen.
7. TMB Substrate Solution B	Not a carcinogen/mutagen.
8. 2N Sulfuric Acid	IARC Category 1

**11.6) Additional Toxicological Information:**

Not found.

**12) Ecological Information (Possible environmental Effects behavior and fate):**

2N Sulfuric Acid: Water hazard class 2: hazardous for water.

Other liquid components: Water hazard class 1: slightly hazardous for water.

Do not allow undiluted liquid components or large quantities of the liquid components to reach ground water, water course or sewage system.

**13) Disposal Considerations:**

Components	Recommended Disposal Methods for components/contaminated components/used components.
1. Plate	Treated as potential infectious materials before disposal.
2. HRPO Conjugate Solution	Treated as potential infectious materials before disposal.
3. Negative Control	Treated as potential infectious materials before disposal.
4. Positive Control	Treated as potential infectious materials before disposal.
5. Washing Solution D (20X)	Diluted with large quantities of water.
6. TMB substrate Solution A	No special measures required.
7. TMB Substrate Solution B	No special measures required.
8. 2N Sulfuric Acid	Neutralized with base and/or diluted with large quantities of water.
Specimens	Treated as potential infectious materials before disposal.

**14) Transport Information****14.1) Land Transport ADR/RID:**

2N Sulfuric Acid: ADR/RID Class: 8 Corrosive Substances

UN Number: UN2796

Packaging Group: II

Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.

Other components: ADR/RID Class: None

**14.2) Maritime Transport IMDG:**

2N Sulfuric Acid: IMDG Class: 8

UN Number: UN2796

Packaging Group: II

Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.

Other components: IMDG Class: None

**14.3) Air Transport ICAO-Ti and IATA\_DGR:**

2N Sulfuric Acid: ICAO/IATA Class: 8

UN Number: UN2796

Packaging Group: II

Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.

Other components: ICAO/IATA Class: None

**15) Regulations:**

**15.1) Product Related Hazard Information:**

Observe the general safety regulations when handling the kit, its components and specimens.

**15.2) Labeling according to EU guidelines/NFPA chemical Hazard Labels:**

The kit including its components will be classified and marked in accordance with EU Directives/NFPA Chemical Hazard Labels.

**15.3) Information about limitation of use:**

The kit and its components are for in vitro diagnosis use and for professional use only.

**15.4) Code letter, risk phrases, safety phrases and hazard designation of the kit and its components:**

Please see 2.3) and 3.1) of this MSDS.

**16) Other Information:**

This MSDS is based on our present knowledge. However, it is intended only as a guide to the appropriate precautionary handling of the kit and its components for professional use. Individuals receiving this MSDS must exercise their independent judgment in determining its appropriateness for a particular purpose.